

REMARKS

Claims 1, 3-8, 10-24, 26-29, 31-46, 99 and 100 are pending in this application. Claims 1 and 39 have been amended to further define the invention. Support for this amendment may be found in the specification at various locations, including page 5, line 32 to page 6, line 2.

The specification has been amended to remove the “www.” portion of certain hyperlinks for browser-executable code. In addition, amendments have been made to correct typographical errors identified by the Examiner. No new matter has been added.

Specification

The Examiner has also objected to the specification for containing an embedded hyperlink or other browser executable code on page 9 and other pages. Applicants previously deleted all instances of “http://” and the symbols “<>” surrounding a URL. The Examiner has requested that additionally, the “www.” in the URLs be removed. By this amendment, Applicants have deleted the “www.” portions of URLs. Thus, it is believed that this amendment overcomes the objection. Withdrawal of the objection is respectfully requested.

Rejections Under 35 USC § 112, Second Paragraph

Two office actions ago, the Examiner indicated that then pending claims 30 and 39 would be allowable if rewritten in independent form including all limitations of the base claims. Applicants took this action, but instead of receiving a notice of allowance, they received two successive office actions, each with new objections and rejections that could have been raised earlier. Applicants respectfully request an end to this piecemeal prosecution.

Claim language, which was essentially unchanged over the course of multiple actions is now challenged by the Examiner under section 112, second paragraph. Presently, claims 1, 3-8, 10-24, 26-29, 31-46, 99 and 100 stand rejected under 35 USC §112, second paragraph as allegedly being indefinite.

In the first rejection under section 112, second paragraph, the Examiner contends that the meaning of the following phrase in claims 1 and 39 is unclear: “which character strings, when aligned for maximum identity, comprise at least one region of heterology.” While Applicants

believe the phrase is clear and definite, they have nevertheless amended claims to explicitly recite that “each parental character string when so aligned contains areas of identity and areas of heterology with any other parental character string.” It is believed that this feature of the claims was implicit in earlier versions. It is also referenced at various locations in the specification, including page 5, line 32 to page 6, line 2.

Applicants note that in framing this rejection, the Examiner states

It is not clear whether the sequence in the “region of heterology” is different in each and every one of the plurality of parental character strings or only in some thereof.

Applicants believe that the above amendment addresses this concern. But possibly the Examiner is questioning whether the claims require that the sequences of the region of heterology for any pair of parental character strings be different from the sequences of the regions of heterology for every other pair of parental character strings. The claim does not state this and it is not required. For example, a region of heterology between the strings of pair 1 might present the same sequences as a region of heterology between strings of pair 2. However, pair 1 might have a separate region of heterology not represented in pair 2. Or a member of pair 2 might have additional or removed terminal sequences not present in a counterpart member of pair 1. All of these scenarios should be considered to be covered by the claims. It is respectfully submitted that this fact does not render the claims indefinite. Claims are not indefinite merely because they read on multiple embodiments.

Next, the Examiner contends that the meaning of “providing a set of oligonucleotides corresponding to the set of characters strings subsequences” in claims 1 and 39 is unclear. Specifically, the Examiner states that

It is not clear whether the oligonucleotides provided correspond to subsequences by having the same sequences thereof, or by having sequence complementary to the subsequences.

Both situations are covered by the claims. It is respectfully submitted that this level of breadth does not render the claims unclear or indefinite under section 112, second paragraph. See MPEP 2173.04. While claims must meet a threshold level of clarity, MPEP section 2173.02 explains the requirement as follows:

The essential inquiry pertaining to this requirement is whether the claims set out and circumscribe a particular subject matter with a reasonable degree of clarity and particularity. Definiteness of claim language must be analyzed, not in a vacuum, but in light of:

- (A) The content of the particular application disclosure;
- (B) The teachings of the prior art; and
- (C) The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made.

The term “correspond” as used in the claims and specification would be readily understood by person of skill in the art at the time of the invention to include both situations raised by the Examiner: identical sequences and complementary sequences. Withdrawal of the rejection is respectfully requested.

Next, the Examiner questions the meaning of the phrase “wherein the subsequences from each parental character string are separated by a crossover point” in claims 1 and 39. Because claim 39 does not include this phrase, the rejection will be addressed for claim 1 only.

The Examiner presents three specific concerns about this phrase. For the first two, the Examiner indicates that “the subsequences from each parental character string” in claim 1 lacks clear antecedent basis and is not clearly trackable to earlier references in the claims. To address this concern, claim 1 has been amended to reference “the chimeric nucleic acid” when referring to the crossover point feature in line 19.

Concerning the same claim language, the Examiner’s third concern is presented as follows:

It is not clear whether the crossover point is within a subsequence represented by an oligonucleotide that comprises a chimeric sequence comprising a subsequence from each of at least two parental character strings, as recited in lines 16-18, or the crossover point is between two subsequences, each of which represented by an oligonucleotide provided.

The amendment discussed immediately above addresses this concern. Withdrawal of the rejection is respectfully requested.

Finally, the Examiner rejects the claims based on the phrase “wherein at least one crossover point for at least one oligonucleotide member is selected from a region outside of an identified pairwise homology region.” Claims 1 and 39 are cited in this regard. However, because the recited phrase does not appear in claim 39, the rejection will not be addressed with respect to that claim.

The Examiner’s concern is explained as follows:

It is not clear whether the crossover point is outside of all pairwise regions of all the parental character strings, or it is just outside of “an pairwise region” because “a region outside of an identified pairwise homology regions” of two parental strings could well be inside of a pairwise homology region of two other parental strings.

Applicants respectfully point out that the claim covers all situations where the crossover point is outside “identified pairwise homology regions,” regardless of whether the crossover point is inside any other regions of pairwise homology for any other parental strings. The fact that the claim covers this situation does not make it unclear. The plain language of the claim indicates that it should be interpreted this broadly. Again, the fact that a claim is broad enough to read on multiple embodiments does not in itself render the claim unclear or indefinite under section 112, second paragraph. See MPEP 2173.04.

In view of the above, Applicants request that the Examiner withdraw all rejections under 35 USC § 112, 2nd paragraph.

Rejections Under 35 USC § 112, First Paragraph

All pending claims were rejected under this section for the following reason:

the specification, while being enabling for annealing members of a set of oligonucleotides corresponding to a set of character string subsequences, wherein each of the oligonucleotides is complementary to at least one other oligonucleotide of the set, does not reasonably provide enablement for annealing members of the set of oligonucleotides wherein none of the oligonucleotides is complementary to at least one other oligonucleotide.

The *Wands* factors were then cited and applied.

As an initial matter, Applicants wish to point out that in order for the annealing and elongating operations to be effective, only portions of oligonucleotides need be complementary with one another. Thus, as long as there is some overlap/complementarity between some of the

members of the claimed set of oligonucleotides, then the annealing and elongating can be implemented using only routine skill. Individual oligonucleotides need not be fully complementary in order to perform the invention.

Regarding enablement of the claims, it appears that the Examiner's position is premised on a reading of the claims in which the claims cover too many inoperative embodiments (embodiments where "none of the oligonucleotides is complementary to at least one other oligonucleotide"). In response, Applicants point out that independent claims 1 and 39 recite "annealing members of the set of oligonucleotides with one another." Annealing presupposes the use of an overlapping set of oligonucleotides. Thus, this claim limitation in itself focuses the claims on operative embodiments. The claims therefore meet the enablement requirement. One of skill in the art would automatically understand how to choose parental sequences and the set of character string subsequences to permit complementary overlap and therefore annealing. Undue experimentation would not be required.

In addition, independent claims 1 and 39 have been amended to explicitly recite that each parental character string, when aligned for maximum identity, comprises "areas of identity . . . with any other parental character string." As such, "the set of oligonucleotides corresponding to the set of character subsequences" will in many cases necessarily possess some overlap with one another (due to the regions of identity) and therefore permit annealing and the other operations recited in the independent claims. This new recitation further reduces the risk of significant numbers of inoperative embodiments. Those of skill in the art possess sufficient expertise to ensure an appropriate choice of parental character strings and a definition of the "set of character string subsequences" such that operative embodiments are promoted and undue experimentation is not required.

The Examiner makes much of the fact that one might encounter embodiments in which oligonucleotides are chosen that do not possess any complementarity. However, when considering the level of skill in the art (undergraduate and even high school students understand what is required for sequences to complementary) one can see that undue experimentation would not be required to enable the claims. Further, as mentioned, the mere fact that the claims require annealing presupposes that the chosen oligonucleotides have some level of overlap and complementarity.

In view of the above, it is respectfully submitted that the *Wands* factors, when applied to the claimed invention and what is reasonably within the possession of those skilled in the art, indicate that claimed methods do not require undue experimentation. Withdrawal of the rejection under 35 USC § 112, First Paragraph is respectfully requested.

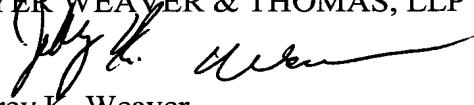
Conclusion

Applicants believe that all pending claims are allowable and respectfully requests a Notice of Allowance for this application from the Examiner. Should the Examiner believe that a telephone conference would expedite the prosecution of this application, the undersigned can be reached at the telephone number set out below.

Applicants believe that no fee beyond the one month extension is required with this filing; however, if it is determined that fees are due, Applicants hereby authorize the Director to charge the required fees to Deposit Account No. 500388 (MXGP001X2).

Respectfully submitted,

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